MAY - 8 2012

510(k) Summary for AmerCare C2 Powder Free Polyethylene Examination Glove

1. Submission Sponsor

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FDA Establishment Registration #: 1053331

2. Submission Correspondent

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3. Date Prepared

Summary Prepared: April 5th, 2012

4. Device Name

Trade/Proprietary Name: C2 Powder Free Polyethylene Examination Glove
Common/Usual Name: Patient Examination Glove
Classification Name: Patient Examination Glove
Classification Regulation: 880.6250
Classification Panel: 880 General Hospital
Product Code: LZA
Device Class: 1

Predicate Device

K110944 Non-sterile Powder Free Vinyl Patient Examination Gloves Clear (non)colored

5. Device Description

Patient Examination glove – Disposable- Single use only – Non-sterile

- The C2 Powder Free Polyethylene Examination Gloves are made of translucent (clear), Low Density Polyethylene material and are powder free. The C2 Powder Free Polyethylene Examination Gloves come in five sizes: Small, Medium, Large, X Large and XX Large. The gloves are loose fitting.

Physical Dimensions	C2 Powder Free Polyethylene Examination Gloves	FDA Recognized consensus standard ASTM D 5250-06
Overall Length:	255 ± 5 mm	230 mm minimum
Width:	105 ± 5 mm (for large glove)	105 ± 5 mm (for large glove)
Palm thickness:	.08mm minimum	.08mm minimum
Finger thickness:	.05mm minimum	.05mm minimum
Tensile Strength		
Before Aging	11 MPa minimum	11 MPa minimum
After Aging	11 MPa minimum	11 MPa minimum
Ultimate Elongation		
Before Aging	300% minimum	300% minimum
After Aging	300% minimum	300% minimum
Pinhole AQL	2.5	2.5

The AmerCare C2 Powder Free Polyethylene Examination Glove meets all current specifications under ASTM 5250-06 Standard Specification for Poly (vinyl chloride) Gloves for Medical Application.

6. Intended Use

A powder-free, non-sterile patient examination glove is a disposable device intended for medical purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

7. Technological Characteristics and Substantial Equivalence

AmerCare Inc. believes that the C2 Powder Free Polyethylene Examination Gloves, 510(k) number K113639, are substantially equivalent to the predicate gloves manufactured by Wanga Plastic Co. Ltd., Powder Free Vinyl Examination Glove, 510(k) Number K110944. The proposed device and predicate device use a similar plastic flexible barrier film to achieve a device for the intended use.

The properties of the C2 Powder Free Polyethylene Examination Glove and Wanga Plastic Co. Ltd., Powder Free Vinyl Examination Glove are compared in the following table. [The header repeats on each page.]

Manufacturer	AmerCare Inc. Proposed Glove	Wanga Plastic Co. Ltd. Predicate Glove	Proposed Glove Compared To Wanga Predicate Glove
Trade name	C2 Powder Free Poly-ethylene Examination Glove	Powder Free Vinyl Examination Glove	Comparable
510(k) number	K113639	K110944	
Product code	LZA	LYZ	Comparable
Regulation #	880.6250	880.6250	Same
Regulation name	Patient Examination Glove	Patient Examination Glove	Same
Indication for use	A powder-free, non-sterile patient examination glove is a disposable device intended for medical purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Non-sterile powder free vinyl patient examination glove, Clear (noncolored) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Comparable
Barrier Film Material	Polyethylene	Vinyl	Comparable synthetic polymer flexible barrier films
Color	Translucent [clear]	Translucent [clear]	Same
Biocompatible	Not a Primary Skin Irritant; Not a Dermal Sensitizer	Not a Primary Skin Irritation; Not a Dermal sensitization	Same
Powder-free	Powder-free per FDA recognized ASTM D6124-06	Powder-free per FDA rec-ognized ASTM D6124-06	Same
Physical properties	Per FDA recognized ASTM D 5250-06	Per FDA recognized ASTM D 5250-06	Same
Freedom from Pinholes	Yes, per FDA 21 CFR 800.20	Yes, Per FDA 21 CFR 800.20	Same
Sizes	S, M, L, XL and XXL	S, M, L and XL	Comparable

The C2 Powder Free Polyethylene Examination Glove from AmerCare Inc., shares the same or comparable indications for use, device operation, biocompatibility, freedom from pinholes, and functional capabilities; therefore, it is substantially equivalent to the predicate device.

8. Non-Clinical Testing

- Physical Testing per ASTM 5250-06 Standard Specification for Poly (vinyl chloride) gloves for medical application
- Powder Free Per ASTM 6124-06 Procedure 1: Residual Powder is 0.18mg
- Water Leakage Testing per US 21CFR 800.20
- Biocompatibility Testing per ISO 10993-1, 10993-5 and 10993-10

9. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing.

10. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the AmerCare C2 Powder Free Polyethylene Examination Glove and the Wanga Plastic Co. Ltd., predicate glove do not raise any questions regarding its safety and effectiveness. The C2 Powder Free Polyethylene Examination Gloves, as designed and manufactured to yield a safe and effective barrier device, are determined to be substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Ty King
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Re: K113639
Trade/Device Name: C2 Powder Free Polyethylene Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: March 28, 2012
Received: April 20, 2012

Dear Mr. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113639

Device Name: C2 Powder Free Polyethylene Examination Gloves

Indications For Use: A powder-free, non-sterile patient examination glove is a disposable device intended for medical purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use __YES__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claus-Williams

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113639